

September 29, 2022

## Get Ready for the Biden Regulatory Agenda

**What's Happening:** Winter is coming. So is the regulatory spring.

**Why It Matters:** Unified Democratic control of the federal government is coming to an end. Given the structural advantages Republicans have with their rural, working-class voters, unified Democratic control may not come back until Taylor Swift [wins](#) the Tennessee Senate race in 2036. Democrats did what they could with the bare-minimum majority this Congress, but the progressive legislative agenda goes dormant next year (although, [plenty will still get done legislatively](#)). This leaves progressives looking towards the executive branch. **In balancing his position in the middle of the Democratic Party and eyeing a likely reelection run in 2024, President Biden wants people to think less about his growing age and more about his growing policy victories. A vigorous regulatory and executive agenda will be at the forefront.** Biden has empowered the progressive wing of the party in key regulatory slots. **This progressive personnel also knows a potential Republican Congress and Republican administration further down the line means it's now or never to get their agenda through the regulatory process.**

**What's Next:** Biden and congressional Democrats still have work to do in order to empower that regulatory agenda. First, they need to get as many vacant positions confirmed through the Senate. **The lame duck session this year will be critical for the confirmations of Gigi Sohn to the Federal Communications Commission, Richard Revesz to the Office of Information and Regulatory Affairs, and Jessica Looman to the Department of Labor's Wage and Hour Division.** This will become even more critical if Republicans win back control of the Senate in the midterms. **Then there's the checks and balances that come with a Republican Congress.** A GOP House and/or Senate may not be able to directly stop a regulatory or executive action. But they hold the purse strings to government funding and the power to hold committee hearings and investigations. A zealous regulatory agenda could lead to a fight over an agency's annual appropriations. Finally, there's the looming courts, which have taken a conservative turn and may have only so much deference to executive action. This can often temper an administration to not go as far as they want with a regulation or executive action. **But key Biden regulators don't blush easily. Expect the reports and proposed rulemakings of today to turn to finalized rules come tomorrow. The Fall 2022 Unified Agenda (UA) should come out at the end of the year or the beginning of next year, providing another guidepost to where things stand.**

The Biden administration isn't atypical in terms of the number of regulations in the pipeline. It's the significance of those regulations that's noteworthy. From the [Spring 2022 UA](#), there were 220 "economically significant" rules under consideration. These are regulations that the agencies estimate to have effects of at least \$100 million. This has [outpaced every administration](#) at this point dating back to President Reagan. The regulatory lead foot will press on the gas pedal even harder over the next two years. Below is our outlook on key regulatory items.

## Financial Regulation

The Securities and Exchange Commission (SEC) continues to be the place to watch for transformational changes to regulation for the financial system. In [his recent appearance](#) before the Senate Banking, Housing, and Urban Affairs Committee, SEC Chair Gary Gensler made clear that he continues to maintain a long to-do list.

- **Equity Market Structure Modernization:** What appears to be the next major action that the agency may take is to issue a series of new rules related to the equities market structure, including possible changes to payment for order flow (PFOF).
  - **Outlook:** The latest indications are that Gensler [will not outright ban the practice](#), but instead introduce new measures to increase transparency, in line with our expectations. The agency has not ruled out the possibility of [creating a system](#) that requires brokerages to route individual investors' orders into auctions where firms would compete to offer the best price for the consumer. Accompanying this may also be new regulations to clarify the requirements for brokerages to provide "best execution," to lower access fees that exchanges charge brokerages in an effort to push more trading on to exchanges, and to change the rebate system exchange operators use to attract trading volume. Gensler is expected to introduce these rules in the coming months, but final decisions have not yet been made.
- **Climate disclosure and ESG:** Per the Spring UA, the SEC plans to issue [its final climate disclosure rule](#) requiring climate disclosures from public companies in October. The agency is also planning for a notice of proposed rulemaking (NPRM) on its [environment, social, and governance \(ESG\) rule](#) in October that aims to achieve greater transparency in sustainability metrics in ESG funds, and, looking further out, the agency is considering an advanced notice of proposed rulemaking (ANPRM) in April 2023 to consider amendments to the [payment from resource extraction](#) rule that requires disclosures of certain types of payments made in the commercial development of oil, natural gas, or minerals from resource extraction issuers.
  - **Outlook:** The climate disclosure rule and ESG have become the subjects of increased political targeting on the right since their introduction. It is likely that a coalition of Republican lawmakers will sue if and when these rules are finalized and they will face increased scrutiny due to the *West Virginia v. EPA* decision. But the Biden administration and defenders of the rules continue to say they will pursue them and that they are within legal grounds. Last week, the SEC's advisory panel on investor issues endorsed the climate disclosure rule and recommended that the SEC move forward with it. This is not binding

but underscores the support for the proposal, though Republican SEC Commissioner Hester Peirce at the same meeting expressed concern over the cost of the rule. SEC Chair Gary Gensler has previously expressed concern over the rule's ability to withstand judicial review. **A final rule could come by the end of this year as well as the next steps in the ESG-related rules.**

- **Crypto:** Both the SEC and Commodity Futures Trading Commission's (CFTC) primary strategy for regulating crypto continues to be "regulation by enforcement." There had been industry hopes that the CFTC would not embrace this tactic, but a rising number of enforcement actions from the agency suggest that it will. There are, however, a small number of crypto-related rules that we are keeping an eye on.
  - **Outlook:** The two that should be watched closest are those pertaining to virtual wallets and anti-money laundering/know-your-customer requirements from the Treasury Department's Financial Crimes Enforcement Network (FinCEN). These rules had both been initially proposed under the Trump administration and subject to intense industry pushback, but Biden administration officials have made clear that they feel there is value in issuing these regulations. **The focus on bringing these rules to crypto should also be less surprising following the [Treasury Department's sanctions on Tornado Cash](#).** It is clear that there is a desire to limit the ability to use digital assets for illicit actions and these rules would support that effort. In addition to these rules from FinCEN, there are two SEC-proposed rules that while not written explicitly for crypto, may have implications for crypto exchanges and decentralized finance. Industry stakeholders have called for rewriting the rules to ensure that there are not these "unintended" effects, but neither Gensler nor other SEC officials have given any indication as to whether they will address these concerns before issuing the final rules.
- **US-China Audit Agreement:** Gensler views the agreement as a step in the right direction, but emphasizes that the proof will be in the pudding.
  - **Outlook:** The first audits started earlier this month now and are expected to be done before the end of the year. Little has been reported on the progress of these so far, but if there were major issues it is probable that there would have been reports of that. Officials have also [raised concerns](#) about Chinese companies switching to use US-based auditors as they worry that the new auditor may not be able to fully access the company's financials.
- **Gamification/Digital Engagement Practices (DEPs):** Gensler has said the staff is working on recommendations "to address the conflicts of interest and sales practices in light of the increased use of predictive data analytics."
  - **Outlook:** One speculated reform about these practices would be to clarify that they have to comply with Regulation BI as they currently exist in a gray area. This could be done through a formal rulemaking or some have suggested it could happen through an enforcement action. Any rulemaking in this space is likely to cover robo-advisers as well.

## Consumer Finance

Despite the Supreme Court's decision in *West Virginia v. EPA* and the [recent lawsuit against the Consumer Financial Protection Bureau \(CFPB\) from a number of prominent trade associations](#) including the US Chamber of Commerce, American Bankers Association, and Consumer Bankers Association, **we do not expect any changes in the policy agenda of the bureau's progressive director, Rohit Chopra, until he is forced to change course by a federal court ruling.** With that view in mind, over the next few months the bureau will continue to advance several rulemakings and will publish additional studies based on data collected from companies that are under scrutiny. Among the areas in which we expect the bureau to make news are: buy-now, pay-later (BNPL) lending; consumer data privacy, including weighing in on the Federal Trade Commission's (FTC) surveillance rule; small business lending; consumer access to financial data; and redrafting rules around credit card late fees.

As always, Chopra will also be looking at investigations and enforcement actions, including regulation via enforcement in the area of racial discrimination, as his regulatory division begins the arduous process of finalizing what we expect to be a voluminous number of policy changes by 2024, well in advance of the period when a potential unified Republican government can use the Congressional Review Act to nullify any recently finalized rules.

- **Buy-Now, Pay-Later:** The CFPB has issued its long-awaited [report on the BNPL sector](#). While the lengthy and detailed report is important for the Washington-centric process of drafting new rules to govern the business practices of the sector, it is [Chopra's remarks](#) and his statements on “next steps” that matter the most for investors.
  - **Outlook:** Chopra has said that BNPL is merely “a vague marketing term” and that in reality BNPL as a product is “a credit card that incorporates infomercial-style payment plans.” Chopra has mixed feelings about BNPL as a product and says, “I believe that Buy Now, Pay Later can grow and serve consumers well if we can collectively address some of the gaps I’ve just outlined.” These “gaps” are a few of the key areas we have been flagging for several months that will make BNPL lending much closer to that of an open-ended credit card from a regulatory perspective.

**Among the structural issues that he raises are a lack of dispute resolution protections that are mandated in the CARD Act; comparable disclosure terms that would be mandated by the Truth in Lending Act; conducting an ability to repay analysis before offering credit, as mandated by the CARD Act; a ban on requirements for auto-repayment out of a checking account as laid out in the Electronic Funds Transfer Act; and a mandate for any penalty fee to be “reasonable and proportional” as laid out in the CARD Act.**

Chopra says that he has “asked our staff to identify potential interpretive guidance or rules to issue with the goal of ensuring that Buy Now, Pay Later firms adhere to many of the baseline protections that Congress has already established for credit cards” — effectively the rules listed above. **We expect that the bureau will release additional information in this regard in the coming months and that it will finalize its guidance or rules sometime in 2023.** In the meantime, there is always the risk that one or more of the biggest players will be subject to an enforcement action and have to comply with

these rules even earlier — so-called regulation by enforcement.

Other related rules that Chopra discusses include new reporting requirements for BNPL loans to credit reporting agencies so that there is standardization across the industry and other lenders are able to get an accurate sense of the consumer's indebtedness — otherwise the ability to repay analysis would be inaccurate and put consumers at risk. There is also the authority to conduct examinations of BNPL companies and Chopra asks industry to “self-identify” and voluntarily submit to exams, although he also says that the bureau is “reviewing our appropriate authorities to conduct examinations on a compulsory basis, as well.”

Based on this report, it appears that the BNPL sector has reached its high-water mark and multiple significant changes will be coming for all of its practices and lines of business in the near future.

- **Consumer Data Privacy:** In addition to these basic changes that will be mandated for the business practices of BNPL companies, there is an even larger issue which concerns Chopra and could have a yet bigger long-term impact on the sector and on partner retail companies. The report takes great pains to detail how most BNPL companies, among others, are building their businesses around what the bureau calls “digital surveillance.”
  - **Outlook:** Although lengthy, Chopra's summary of how he thinks of BNPL and other market participants' use of consumer financial data is important for investors to understand. He said: “In some ways, these firms aren't just lenders, they are also advertisers and virtual mall operators. Because they are deeply embedded as a payment mechanism for e-commerce, Buy Now, Pay Later lenders can gather extraordinarily detailed information about your purchase behavior, in a way traditional cards cannot. Buy Now, Pay Later has mimicked parts of Big Tech's surveillance model to harvest and monetize data in ways that banks and credit unions have typically avoided. Many of these firms have created their own gateways and digital, app-driven marketplaces, powered by personalized behavioral data, to lure their users into buying more products financed through a Buy Now, Pay Later loan. Increasingly, Buy Now, Pay Later firms can leverage data and user interface design to gamify shopping and lending, promoting repeat usage and further revenue generation.”

**The potential for these companies to use digital dark patterns and pricing based on consumer behavior is too risky for Chopra and we expect that he will use rulemaking authority to squelch these practices for any company that offers credit as a consumer finance company.** He cites the fact that in the US there is a long history of a separation between commerce and banking and we expect that he will attempt to return to the status quo ante.

Specifically, Chopra has tasked bureau staff with “identify[ing] the data surveillance practices that Buy Now, Pay Later providers engage in that may need to be curtailed.” He goes on to mention demographic, transactional, and behavioral data that is used outside of a lending decision and links these practices to wider concerns with Big Tech companies. **Chopra then goes**

even further and cites the ongoing FTC rule on commercial surveillance and says the bureau will participate in drafting this rule and will be responsible for enforcing it for financial services firms — effectively using the legal authority of another agency to curb the business practices of a whole industry.

This announcement means that investors with an interest in BNPL should also pay close attention to the [FTC rulemaking on commercial surveillance](#) as it will have a significant impact on the future lines of business that BNPL companies can conduct.

- **Small Business Lending Data Under The Equal Credit Opportunity Act:** The CFPB is working to finalize a [rule to create a new mandate for lenders to collect racial and other data on borrowers and potential borrowers](#).
  - **Outlook:** Although collection of such data creates costs for lenders, it is what we expect the CFPB will do with the data that is most important, once the final rule is issued in 2023. Once the CFPB has access to data about how lenders interact with those seeking loans, then it will be able to use it to determine whether any discrimination (intentional or not) has occurred. It will most likely use the disparate impact standard or its new policy of racial discrimination being “unfair” as a part of the bureau’s UDAAP (unfair, deceptive, abusive, acts and practices) authority. The CFPB does not shy away from this characterization, writing in the Spring UA preamble, “Congress enacted section 1071 for the purpose of (1) facilitating enforcement of fair lending laws and (2) enabling communities, governmental entities, and creditors to identify business and community development needs and opportunities for women-owned, minority-owned, and small businesses.”
- **Consumer Access to Financial Records:** Section 1033 of the Dodd-Frank Act provides that the bureau can promulgate rules that a regulated entity must provide to a consumer, upon request, access to their financial records and transaction data from any product or service that is used by the consumer. In November 2020, an ANPRM was issued and comments were accepted until February 2021. The next step is that the bureau will convene a Small Business Regulatory Enforcement Fairness Act hearing in November 2022, and then a final rule will be issued, likely sometime in 2023.
  - **Outlook:** We expect that this rule will cover more limited aspects of consumer financial data privacy due to the narrow way the law was written and the bureau will put more of its energy into the aforementioned FTC regulation on commercial surveillance.
- **Credit Card Late Fees:** CFPB Director Chopra has telegraphed that the bureau plans to issue a proposed rulemaking on credit card late fees next year. A review of credit card issuers’ penalty policies as part of the pre-rule work on this issue has already been initiated.
  - **Outlook:** The proposed rule would end the peg of credit card late fees to inflation, remove the safe harbor for issuing banks created by the Federal Reserve Board when it drafted the implementing rules of the CARD Act, and create new rules to materially limit allowable late fees

**and subject card-issuing banks to enforcement action if the fees (over \$12 billion last year) are found to be discriminatory.** Under the existing rules, it is expected that next year the vast majority of banks will raise their late fees to \$33 for the first late payment and \$45 for subsequent late payments.

We expect that Chopra will seek to substantially decrease the amounts that can be charged, compared to the status quo, as well as limit future increases so they do not automatically adjust based on inflation. At a recent event, Chopra said, "The Fed created a set of immunity provisions that has been going up by inflation every year and so we are going to be reviewing whether that number makes sense or whether there needs to be a new framework on it. We are hoping to be able to complete that process by next year..it would go through a rulemaking process. When a business model is heavily dependent on penalty fees, I think that's where you have to question if that's distortionary to the competitive process."

In June, the bureau [issued an ANPRM](#) soliciting comments "from credit card issuers, consumer groups, and the public regarding credit card late fees and late payments, and card issuers' revenue and expenses." Perhaps the key question asked by the bureau in the ANPRM was about the phrase "reasonable and proportional" in the statute in regard to any late fee. Although this phrasing is used in the law, the safe harbor created by the Federal Reserve Board's implementing rulemaking does not require any type of analysis to determine where a fee is reasonable or proportional.

Chopra is also worried about the fees being used to drive revenue, rather than as a deterrent. He said, "Rather than [late fees] being a simple deterrent, are some credit card companies building that in as a core revenue driver? We inherited a system from the Federal Reserve Board of very, very complicated regulations that really in many ways seem designed to fit the business models of the largest institutions rather than having clear, bright lines."

**These are the justifications that we expect Chopra will use in reopening the rules implementing the law and dramatically slashing late fees, removing billions of dollars from card issuing banks. Investors should look to determine which banks earn the most revenue from these fees and those are the institutions that are potentially most at risk, since we do not expect any additional regulatory efforts related to credit cards in the foreseeable future.**

## Energy and Environment

For climate and environmental regulations, the first half of Biden's term has focused largely on reversing Trump-era rollbacks. This has led some activists to complain that the regulatory agenda has not been aggressive enough in reining in emissions and enforcing pollution requirements and environmental justice principles. And there is truth in that the regulatory agenda may have been sidelined – and held back so as not to upset certain Democratic senators – while the Biden administration was focused on climate legislation in what ultimately passed in the Inflation Reduction Act (IRA). But the White House is visibly beginning to focus more on these priorities with a recent example being the establishment

of a new Office of Environmental Justice and External Civil Rights within the Environmental Protection Agency (EPA) and the focus on the nomination of Richard Revesz, an expert on environmental litigation, to the Office of Information and Regulatory Affairs.

Another factor that likely has delayed environmental regulations is the Supreme Court decision in *West Virginia v. EPA*, which has thrown into question the power of federal agencies to enact regulations if they are deemed to be outside of their statutory authority delegated by Congress. However, likely countering the influence of that decision for climate policies is the language included within the IRA that states that carbon dioxide is a type of air pollution covered by the Clean Air Act (CAA). The CAA serves as the legal basis for a number of significant emissions and air pollution regulations and this language will offer additional legal protection if and when litigation over rules arises.

- **PFAS:** The Biden administration is sticking to its plans to act on its aggressive regulatory strategy to reduce and clean up per- and polyfluoroalkyl substances referred to collectively as PFAS. The latest and most significant step to date is the EPA [statement](#) that it will publish an NPRM in the “next several weeks” to designate PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act, also known as “Superfund.” Under the Spring UA, the NPRM is due by November.
  - **Outlook:** The proposed rule would apply to two types of PFAS -- perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) – and its publication will begin a 60-day public comment period that is sure to see a range of input. The hazardous substance designation is the most consequential regulation that the Biden administration can enact because of its legal teeth. It would trigger strict liability standards under Superfund requiring all companies involved in producing, transporting, or using PFAS to help pay for its cleanup. If finalized, it will kick off a large and complex regulatory process for the EPA to oversee given how widespread PFAS is in the environment as well as the inevitable industry pushback and litigation. It will also likely result in high costs to the government, including the Department of Defense, which has opposed the measure due to the use of PFAS in firefighting foam. Headline risk will be a factor as PFAS has brought [high settlements](#) in cases already, and litigation could stretch for years to sort out liability. While **3M (MMM)** and **Chemours (CC)** are the more high-profile examples of companies involved in PFAS – as producers – the breadth of coverage in the Superfund law will implicate more companies that owned or operated a PFAS contaminated site.

Illustrating this is that the US Chamber of Commerce opposes the rule alongside trade groups representing clothing and footwear manufacturers, oil companies, and the paper and packing industries. The EPA did address this cost to business in its press release – “the proposed rule would, in certain circumstances, facilitate making the polluter pay by allowing EPA to seek to recover cleanup costs from a potentially responsible party or to require such a party to conduct the cleanup” – but first focused on the ability of a final rule to force reporting of PFOA and PFOS releases to federal and tribal authorities. Some Republicans have already painted the effort as an unnecessary and burdensome regulation for businesses, which will make communicating the health and environmental risks of the substances a priority for the Biden administration. Ultimately, President Biden and EPA Administrator Michael



Regan will bear the responsibility for implementing this regulatory plan even as legal questions over its enforcement could play out well beyond both of their political tenures.

- **Renewable Fuel Standard (RFS):** The EPA said in the Spring UA that it will issue a NPRM on biofuel blending requirements for 2023 and beyond under the RFS in September and a final rule by April of next year.
  - **Outlook:** The EPA has not yet acted on its step slated for this month. 2023 is the first year that Congress will not provide statutorily mandated blending volume requirements and the process is now turned over to the EPA. The new blending requirements are significant to oil refining and biofuel industries. Earlier this year the agency sought to ramp up the biofuel levels required for 2022 but later retroactively reduced the 2020 targets. A senior EPA official has said that the agency is constrained in using the program to enact a low-carbon fuel standard due to the statutory obligations around blending requirements. Biofuel companies are calling for aggressive volumes.
- **Emissions at power plants:** The EPA pushed back its plans to propose a new rule to regulate emissions at power plants that is intended as a broad replacement to the Obama administration's Clean Power Plan and the Trump administration's Affordable Clean Energy Rule.
  - **Outlook:** The EPA is still looking to propose a rule or set of rules to reduce carbon emissions at power plants and this summer held a series of meetings with stakeholders and experts considering the options to do so under the CAA. Another sign suggesting they are pursuing this is the opening of a nonregulatory [docket](#) to solicit written input from “a broad group of stakeholders.” These meetings and comments are expected to help guide the agency in regrouping after the *West Virginia v. EPA* case to craft a rule that will stand up to judicial review. According to EPA, the new target for these rules is by the end of the first quarter of 2023.

## Privacy

Comprehensive data privacy legislation in the form of the American Data Privacy and Protection Act (ADPPA) is under consideration in Congress, but the FTC is also honing in on the issue. **In August, the FTC [announced](#) a significant rulemaking on what it terms “commercial surveillance,” in addition to data security.** In a [statement](#), FTC Commissioner Alvaro Bedoya said that the FTC’s ANPR on data privacy will not conflict with the ADPPA. “This ANPR will not interfere with that effort. I want to be clear: Should the ADPPA pass, I will not vote for any rule that overlaps with it. There are no grounds to point to this process as reason to delay passage of that legislation.” **With the ADDPA looking unlikely to pass this year (for reasons we described in a recent [Spotlight Report](#)), the FTC rulemaking may be the more likely pathway for comprehensive federal data privacy protections to be enacted in the near future.**

- **Trade Regulation Rule on Commercial Surveillance:** The purpose of [this rule](#) is to “curb lax security practices, limit privacy abuses, and ensure that algorithmic decision-making does not result in unlawful discrimination.” According to a [fact sheet](#) released by the FTC, some specific areas of interest for the commission include inadequate data security practices, the impact of commercial surveillance on

children, consumer-unfriendly data collection practices, inaccurate and discriminatory effects of algorithms, and dark patterns.

- **Outlook:** This rulemaking is currently subject to a public comment period, which will end October 21st. The timeline has slipped from the Spring UA, which estimated that the comment period would end in August of this year. Instead, the FTC released its notice of proposed rulemaking in August. Delays should be seen not as a lack of commitment to the rulemaking on the part of the FTC, but rather a reflection of the complexity of the effort the agency is undergoing. This rule is also the one referenced earlier, on which the CFPB plans to offer input and use to enforce against companies operating in the consumer finance sector.
- **Children's Online Privacy Protection Rule:** The FTC is continuing to review public comments submitted in 2019 regarding the [agency's rule](#) that implements the Children's Online Privacy Protection (COPPA) Act.
  - **Outlook:** It's not yet clear when the FTC will finish evaluating public input on its COPPA rule, but the issue of children's privacy appears to be rising in stature at the commission. In a [speech](#) delivered last week at the National Advertising Division Annual Conference, Bedoya identified "the potential mental health harms to children and teenagers stemming from prolonged use of social media" as a priority, and in May, FTC commissioners unanimously approved a new [policy statement](#) on the agency's enforcement of COPPA relating to education technology.

## Gig Economy

President Biden's public stance on labor is undimmed in his second year in office. For example, he marked Labor Day with an event in Wisconsin during which he [championed](#) organized labor; in June, he spoke at the AFL-CIO's convention in Philadelphia and reinforced his commitment to being "the most pro-union president in history"; and in May, the Biden administration took the [symbolic action](#) of inviting labor organizers, including those from high-profile unionization campaigns at **Starbucks (SBUX)** and **Amazon (AMZN)**, to the White House. Beyond the president's strong rhetoric on labor, however, his policy record is more mixed. Until the announcement of a rulemaking on worker classification this summer, the Biden administration had not taken much concrete action on the gig economy.

- **Worker Classification Rule:** In a [June blog post](#), Jessica Looman, deputy administrator of the Department of Labor's (DOL) Wage and Hour Division, announced that the department will start a new rulemaking on worker classification. It was not included in the Spring UA. It's not entirely clear what the details of this rule will be. Based on President Biden's vocal stance in support of the labor movement and unions, it's likely that the rulemaking will be labor-friendly, but how far it might go is an open question.
  - **Outlook:** In the June announcement, Looman wrote that the misclassification of workers as independent contractors instead of employees "is one of the most serious problems facing affected employees, employers and the U.S. economy," suggesting that the development of this rule will be a priority for the

DOL. Biden has nominated Looman, who is also serving as the acting administrator of the Wage and Hour Division, to take on the role permanently. The DOL is unlikely to release a proposed worker classification rule until after Looman is confirmed, as federal agencies typically don't take major actions under acting leadership. Because Looman is already leading the Wage and Hour Division in an acting capacity, it's likely that DOL will be able to make progress on this matter before her confirmation and have it teed up relatively quickly. Reuters [reported](#) this week that the White House Office of Information and Regulatory Affairs is reviewing the DOL's proposed rule, and the Office of Management and Budget has been holding meetings with interested parties. The next edition of the Biden administration's UA is likely to provide an update on the timeline for this rulemaking.

## Healthcare

The Department of Health and Human Services (HHS) always has an enormous number of rulemakings in various stages on its docket. While most investors with an interest in healthcare tend to focus on the annual payment rate notices for sub sectors like Medicare Advantage, home health, skilled nursing facilities, etc., we have chosen a few rules that we expect to have an impact outside of those annual exercises: implementing guidance for prescription drug pricing reforms from the IRA; nursing home minimum staffing rules; a new nebulous mandatory payment model for Medicare; Medicaid managed care; and the interchangeability of biologics and biosimilars.

- **Prescription Drug Pricing Negotiations:** The IRA passed and was signed into law by Biden in August. The enormous law has several important healthcare provisions, but the most controversial is how HHS plans to implement prescription drug pricing negotiations.

- **Outlook:** We expect that every element of the implementation of drug pricing negotiations will be questioned, if not litigated, by its opponents. Already, [Senate Republicans have written a letter](#) demanding to know how HHS intends to spend the \$3 billion appropriated in the law for standing up the division that will conduct such negotiations. The letter also highlights an important but little-discussed part of the law that does not require a notice and comment rulemaking for setting the parameters for negotiation and standing up the "Drug Price Negotiation Program" and instead, we expect that the Centers for Medicare and Medicaid Services (CMS) will rely on internally produced guidance. This does not mean that CMS will not ask for public comment for ideas on how to implement the negotiation aspect of the law, but it does not have to reply to those comments or take them into consideration when standing up the new program as it would under a traditional notice and comment rulemaking.

- CMS has also given some clues as to how this new group will be organized in [a draft organizational chart of the new division](#), which looks like it will have nearly 100 staff.

Other elements of the law that are not related to price negotiation will have a formal rulemaking period and several of these provisions go into effect in 2023, which means that proposals for their implementation will likely come

towards the end of this year or in early 2023 so they can be finalized and stay within the law. Among the policy areas that are first on the docket are inflation rebates, caps on out-of-pocket spending, and the cap on insulin cost sharing for Medicare beneficiaries.

- **Nursing Home Minimum Staffing Study:** As part of the Biden administration's efforts to focus on private equity ownership of nursing homes, the White House has said that CMS will conduct a research study on minimum staffing needs for these facilities and publish it by early 2023. This study will then be the basis for a rulemaking, supposedly by year end, though that is likely to slip, which will create minimum staffing adequacy numbers for all nursing homes and introduce financial penalties for failing to meet those requirements.
  - **Outlook:** The nursing home focus by the Biden administration is nearly all a political exercise in order to bring negative publicity to private equity ownership in healthcare and to attempt to reward Democratic supporting unions that are prevalent in nursing homes in certain parts of the country. The only aspect of the nursing home agenda that has any teeth and should concern investors is the minimum staffing requirements as they will increase costs and necessitate additional spending for permanent positions. Since there is such a lack of nurses in general and interest in working for nursing homes in particular, we expect that CMS will include some type of maintenance of effort waiver to allow facilities that are making a good faith effort to meet the standards to continue to operate even if they are unable to find sufficient staff. To the extent that this type of safety valve is not included, there will certainly be litigation and a large amount of headline risk.
- **Alternative Payment Model:** This potential rule would create a new mandatory Medicare payment model under section 1115A of the Social Security Act. The purpose of the model is to save money for Medicare while "preserving or enhancing" quality of care for beneficiaries. If the model is deemed to be successful, then it can become a permanent and mandatory policy nationwide.
  - **Outlook:** It is unclear what the topic of the model will be, but **there is a reasonable chance that it is focused on value-based care and that it could be the Biden administration's most important healthcare-focused regulatory action to date.** This type of proposal would add an overlay of value-based care features on top of all Medicare beneficiary doctor/patient relationships and it would be mandatory for all participating doctors. If this is in fact the topic of the model, it will be controversial, but there is nothing to stop the Biden administration from pushing it through if they have the political stomach for any blowback.
- **Medicaid Managed Care:** This rule would propose changes to Medicaid managed care regulations, including additional parameters on states' use of In Lieu of Services or Settings and state-directed payments under Medicaid managed care contracts. We expect that this rule could also include more value-based care policies as well as greater emphasis on equity and data collection to track outcomes.
  - **Outlook:** There has not been a wholesale change to Medicaid managed care in quite some time, as the focus has remained on Medicaid expansion in the wake of the Affordable Care Act. This new proposed rule, scheduled for

February 2023, could have a large impact on the companies that participate in managed Medicaid and is almost certain to impose more costs on them, though there is a chance that there could also be higher reimbursement rates if certain strict improved health equity outcomes are met.

- **Biologics Regulation Modernization:** The Food and Drug Administration (FDA) is considering a rule that would create new interchangeability standards that clearly account for the existence of certain biosimilars and biologics in order to "support competition and enhance consumer choice by preventing efforts to delay or block competition from biosimilars and interchangeable products."
  - **Outlook:** While interchangeability has been controversial, it is not new to investors in drug and biologic manufacturers. The NPRM was previously listed as expected in August but it was listed in the Spring UA as March 2023. We expect that the rule will be finalized with the idea of being able to bring down prices without harming health firmly in mind. Going into the 2024 election, the Biden team is going to be looking for anything it can point to in terms of saving both Medicare and senior citizens money on their prescription drugs and further utilizing interchangeability is one area where savings can be felt.

## Tobacco

The FDA is tightening regulation of tobacco products under the Biden administration, a crackdown that fits with how Biden has made fighting cancer a priority of his presidency. Earlier this month on the 60th anniversary of President Kennedy's speech pledging to put a man on the moon, Biden spoke about his own "[Cancer Moonshot](#)" and voiced an objective of reducing cancer death rates by 50 percent in 25 years. The president's initiative largely focuses on cancer research and care, but the FDA's proposed rules to restrict tobacco also align with the president's goal.

- **Ban on Menthol Cigarettes:** This [proposed rule](#) would block menthol-flavored cigarettes from the US market.
  - **Outlook:** In early August, the FDA's [public comment period](#) on this rulemaking closed, and about 175,000 comments on the menthol ban were received. The FDA will next evaluate the input submitted as it develops a final rule. The tobacco industry is expected to fight the proposed menthol ban and in the face of lobbying and litigation, this rulemaking could potentially slip to near the end of Biden's term or beyond.
- **Ban on Characterizing Flavors in Cigars:** This [proposed rule](#) would block cigars with characterizing flavors other than tobacco (e.g., menthol, fruit, and cocoa) from the US market.
  - **Outlook:** As with the menthol cigarette ban, the flavored cigar ban was the subject of a public comment period that closed last month. About 71,000 comments were received and must be reviewed before the FDA finalizes the rule.
- **Lower Nicotine Tobacco Product Standard:** This [proposed rule](#) would lower the nicotine content in cigarettes to minimally or nonaddictive levels.

- **Outlook:** The time horizon for this rulemaking is likely to be long. The Spring UA gave an estimate of May 2023 for the release of a notice of proposed rulemaking on the nicotine standard. The tobacco industry is virtually certain to fight it aggressively, however, given the risk that this policy would pose to the tobacco market if enacted. According to a New England Journal of Medicine paper cited by the FDA in a June [announcement](#) about the proposed nicotine standard, the rule would reduce the smoking rate from 12.4 percent of Americans to 1.4 percent by 2100. This rulemaking process could easily stretch beyond Biden's term in office, and a potential Republican administration coming into office in January 2025 is less likely to see the effort through.

## Autonomous Vehicles

The Federal Motor Carrier Safety Administration (FMCSA) and National Highway Traffic Safety Administration (NHTSA) have continued work on their respective rulemakings pertaining to autonomous vehicles (AVs). **But progress has been slow. Some of this is likely due to the leadership challenges both agencies have faced.** Robin Hutcheson was confirmed by the Senate just last week to be FMCSA administrator. Hutcheson took over in an acting capacity in January after Biden's initial nominee stepped down. NHTSA had not had any issues until its administrator, Steven Cliff, announced he would be leaving in August after less than three months on the job. NHTSA has an acting head at the moment, but Biden has not announced a new nominee for the permanent role. **This slower rulemaking has a mixed effect on the AV industry.** The upside is that the companies have a chance to continue pushing development without any constraint of regulation, but the danger that comes with this is that there is still a lack of regulatory clarity. Getting clear, federal rules set in place is likely needed for widespread adoption of the technology. There is also the constant risk of a black swan type event that prompts regulators to move much quicker to address the technology out of safety concerns. There are [already questions](#) about **Tesla's (TSLA)** Autopilot safety, which speaks to where regulators are focused on AVs and could be a preview of areas the agencies will prioritize with their regulations.



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